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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,952	10/12/2000	Jerry Pelletier	21715/1010	7855

29933 7590 12/17/2004

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	Application No. 09/689,952	Applicant(s) PELLETIER ET AL.	
	Examiner Chih-Min Kam	Art Unit 1653	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 15 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 15 November 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof. (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 26-33, 35 and 53-74.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☒ The drawing correction filed on 15 November 2004 is a) ☐ approved or b) ☒ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8/9/04.
10. ☒ Other: See Continuation Sheet

  
**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**

Continuation of 2. NOTE: The amendment to the claims does not resolve the current issues under 35 USC 112, first and second paragraphs. In the amendment of November 15, 2004, claims 26, 53, 59, 67 and 74 have been amended; and claims 27, 28, 31-33, 35, 54-56, 60-62, 65-66, 72 and 73 have been cancelled. Applicants' response has been fully considered, however, claims 26, 29, 30, 53, 57-59, 63, 64, 67-71 and 74 are rejected under 35 USC 112, first paragraph, and claims 67-71 are rejected under 35 USC 112, second paragraph.

If applicants' amendment were entered, it would have the following response:

1. Claims 26, 29, 30, 53, 57-59, 63, 64, 67-71 and 74 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for a method of inhibiting bacterial growth or bacterial DNA synthesis of a bacterium, *staphylococcus aureus* (*S. aureus*) in vitro, comprising contacting the bacteria with a specific inhibitor such as bacteriophage 77 ORF 104 peptide (SEQ ID NO:5) which binds to or decreases the activity of a Dnal polypeptide comprising SEQ ID NO:2, SEQ ID NO:16, or SEQ ID NO:18, or its functional fragments or variants, does not reasonably provide enablement for a method of inhibiting bacterial growth or bacterial DNA synthesis of a bacterium in vitro, comprising contacting the bacteria with an inhibitor which binds to or decreases the activity of a polypeptide comprising SEQ ID NO:2, SEQ ID NO:16, or SEQ ID NO:18, or its functional fragments or variants, where the structure of the inhibitor is not defined. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims (see paragraph 7 in the Office Action dated 7/26/04).

In response, applicants indicate the specification provides ample guidance to permit one of skill in the art to make and use the full scope of the claimed invention without undue experimentation, e.g., the specification teaches methods and assays which may be used to identify agents which act as inhibitors of Dnal and are thus useful according to the claimed invention. The specification also teaches the types of agents which one of skill in the art would likely focus on to identify an inhibitor: small organic molecules, peptides, polypeptide, and antibodies, such agents can be compounds related to and variants of 77ORF104; As evidence of the routine nature of using the novel Dnal/77ORF104 interaction to identify additional inhibitors of Dnal, the bacteriophage protein PVLORF16 is identified as an inhibitor of bacterial growth and bacterial DNA synthesis, and was shown to bind to Dnal (see Declaration by Dr. Jerry Pelletier); and Liu et al. (2004, *Nature Biotechnology* 22: 185; a post filing reference) identified 36 small molecules which were shown to inhibit the interaction between Dnal and 77ORF104. Of these, 11 were tested further and found to inhibit bacterial growth. Two of these were examined further and were identified as inhibiting DNA synthesis via Dnal (pages 8-12 of the response).

Applicant's response have been considered, however, the argument is not found persuasive because the specification only discloses expression of bacteriophage 77ORF104 peptide inhibits bacterial growth, the *S. aureus* Dnal homologs are identified as the host target of bacteriophage 77ORF104, and subsequently the bacteriophage protein PVLORF16 is identified as an inhibitor of bacterial growth and bacterial DNA synthesis in the Declaration by Dr. Jerry Pelletier, however, the specification does not provide sufficient teachings on various inhibitors that bind to or decrease the activity of a Dnal polypeptide in a method of inhibiting bacterial growth in vitro as encompassed by the claims, thus it requires further experimentation to identify various inhibitors and to assess their effects in the inhibition of bacterial growth, the experimentation is undue because further research is needed to practice the claimed invention. Regarding reference by Liu et al, a later dated publication cannot supplement an insufficient disclosure in a prior dated application to make it enabling (see MPEP 2164.05(a)).

2. Claims 67-71 are rejected under 35 USC 112, second paragraph as being indefinite because the claim lacks an essential step in the method of inhibiting a bacterial growth. The omitted step is the outcome of the treatment. Claims 68-71 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate the claims have been amended to recite the outcome of the treatment (page 12 of the response). Applicant's response have been considered, however, the argument is not found persuasive because the endpoint of the process has not been indicated.

Continuation of 3. Applicant's reply has overcome the following rejection(s): If entered, the rejection of claims 26, 29, 30, 53, 57-59, 63 and 64 under 35 USC 112, second paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issues under 35 USC 112, first and second paragraphs.

Continuation of 10. Other: See attached Interview Summary; The abstract filed 11/15/04 is acknowledged; The mass of each peak in Fig. 11 is not readable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

CMK  
December 10, 2004

CMK